

Questions for Ballot Vote

March 27, 2014 meeting of the
Molecular and Clinical Genetics Panel

P130017
Cologuard[™]
Exact Sciences Corporation

The following questions relate to the approvability of *Cologuard*.

Question 1

Is there reasonable assurance that *Cologuard* is safe for use in patients who meet the criteria specified in the proposed intended use?

Question 2

Is there reasonable assurance that *Cologuard* is effective for use in the patients who meet the criteria specified in the proposed intended use?

Question 3

In patients who meet the criteria specified in the proposed intended use, do the benefits outweigh the risks for use of *Cologuard*?